

Supplemental Response Dated March 26, 2008

Supplemental Reply to Office Action of September 12, 2007

Remarks:

Applicants express their appreciation for the telephonic interview granted by the Examiners on January 10, 2008. The interview was attended by Examiners Ardin Marschel and Shirley Gembeh and, on behalf of applicants, Messrs. Paul Prestia and Phillip Gonzalez.

Interview Summary

The following prior art references of record were reviewed during the interview: U.S. Patent No. 4,452,817 to Glen et al., PCT Publication No. WO 03/017977 to Meadows et al., U.S. Patent No. 6,140,374 to May et al., and U.S. No. 6,743,436 to Lee et al.

The lipid-free nature of Applicants' claimed compositions was discussed at some length. No agreement was reached with respect to the patentability of Applicants' invention as claimed. It was agreed that a supplemental response would be filed by Applicants more specifically limiting the lipid content of the claimed compositions. The Examiners agreed to give such a limitation careful consideration. In accordance with that discussion, Applicants' claims are amended herewith.

Amendment

With this Supplemental Response, all independent claims (claims 1, 49, 66, 71, 72, 75, and 77) are amended such that the claimed compositions are limited to less than 1% lipid.

Applicants' claimed, substantially lipid free propofol formulation reduces risks of microbial growth. See, e.g., paragraphs 0063, 0065 of Applicants' disclosure as published. Applicants' composition as disclosed and claimed also has no more than 15% total excipients.

The Office Action of September 12, 2007 rejected claims 1, 11-12, 20, 23-37, 39-64 and 71-74 under 35 U.S.C. § 103(a) as unpatentable over U.S. Patent No. 4,452,817 to Glen et al. ("Glen") in view of PCT Publication No. WO 03/017977 to Meadows et al. ("Meadows") further in view of U.S. Patent No. 6,140,374 to May et al. ("May") further in view of U.S. No. 6,743,436 to Lee et al. ("Lee"). Claims 75-78 were also rejected under 35 U.S.C. § 103(a) as unpatentable over Glen in view of Meadows further in view of May further in view of Lee.

Glen is relied upon by the Office Action for its description of a propofol composition comprising approximately 10% polyethylene glycol 200 and approximately 10% Cremophor RH40. See Glen column 6, lines 1-11.

Applicants' claimed invention is distinguishable from Glen on at least two grounds. First, Glen's described composition comprises approximately 20% total excipients; exceeding

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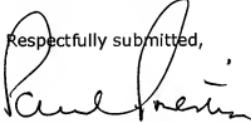
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Applicants' claimed 15% limitation on total excipients. Second, Glen's described composition comprises approximately 10% Cremophor RH40, a modified castor oil; exceeding Applicants' claimed 1% limitation on lipids. Applicants respectfully submit that Glen's description fails to teach these features of Applicants' claimed invention.

Moreover, the Meadows, May and Lee references, taken singly or in combination, fail to provide any information, which in combination with Glen, would inform one of ordinary skill in the art how to make an aqueous propofol composition with less than 15% excipients, and which includes less than 1% lipids. Applicants respectfully submit that on these grounds alone, all of the prior art rejections are improper and should be withdrawn.

Conclusion

Inasmuch as the claim limitations added by this Supplemental Response serve to further distinguish the pending claims from the prior art, Applicants believe the application is in condition for allowance. Early and favorable notification to this effect is respectfully requested.

Respectfully submitted,


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